

**GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2013**

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**SENATE BILL 749\*  
Health Care Committee Substitute Adopted 6/11/14**

Short Title: Strengthen Controlled Substances Monitoring. (Public)

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Sponsors:

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Referred to:

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May 15, 2014

1 A BILL TO BE ENTITLED  
2 AN ACT TO STRENGTHEN THE MONITORING OF CONTROLLED SUBSTANCES.  
3 The General Assembly of North Carolina enacts:

4 **SECTION 1.** Statewide Opioid Prescribing Guidelines.

5 (a) The following State health officials and health care provider licensing boards shall  
6 develop statewide opioid prescribing guidelines that the health care provider occupational  
7 licensing boards shall then adopt:

- 8 (1) The Director of the Division of Public Health of the Department of Health  
9 and Human Services (DHHS).
- 10 (2) The Director of the Division of Medical Assistance, DHHS.
- 11 (3) The Director of the Division of Mental Health, Developmental Disabilities,  
12 and Substance Abuse Services, DHHS.
- 13 (4) The directors of medical, dental, and mental health services within the  
14 Department of Public Safety.
- 15 (5) North Carolina State Board of Dental Examiners.
- 16 (6) North Carolina Board of Nursing.
- 17 (7) North Carolina Board of Podiatry Examiners.
- 18 (8) North Carolina Medical Board.

19 (b) In developing statewide opioid prescribing guidelines, other state and federal  
20 prescribing guidelines shall serve as models to develop and refine North Carolina's prescribing  
21 guidelines. Developers of the guidelines also shall consider establishing opioid dosage  
22 thresholds for physician consultation. The guidelines shall be developed based on the criteria  
23 for clinical practice guidelines set forth by the Institute of Medicine of the National Academies  
24 and shall do all of the following:

- 25 (1) Make recommendations for clinical actions based on review of empirical  
26 evidence.
- 27 (2) Rate the strength of each clinical recommendation.
- 28 (3) Rate the quality of evidence used to support recommendations for clinical  
29 action.
- 30 (4) Explain and assess the benefits and harms associated with options for  
31 alternative treatments.

32 (c) The statewide prescribing guidelines shall be completed by December 31, 2014. The  
33 health care provider occupational licensing boards listed in subsection (a) of this section shall  
34 adopt the opioid prescribing guidelines by no later than July 1, 2015.

35 **SECTION 2.** Continuing Education Requirements.



1 (a) The following health care provider occupational licensing boards shall require  
2 continuing education on the abuse of controlled substances as a condition of license renewal for  
3 health care providers who prescribe controlled substances:

- 4 (1) North Carolina Board of Dental Examiners.
- 5 (2) North Carolina Board of Nursing.
- 6 (3) North Carolina Board of Podiatry Examiners.
- 7 (4) North Carolina Medical Board.

8 (b) In establishing the continuing education standards, the boards listed in subsection  
9 (a) of this section shall require that at least one hour of the total required continuing education  
10 hours consists of a course designed specifically to address prescribing practices. The course  
11 shall include, but not be limited to, instruction on controlled substance prescribing practices  
12 and controlled substance prescribing for chronic pain management.

13 **SECTION 3.** Improve Controlled Substances Reporting System Access and  
14 Utilization.

15 (a) G.S. 90-113.74 reads as rewritten:

16 "**§ 90-113.74. Confidentiality.**

17 (a) Prescription information submitted to the Department is privileged and confidential,  
18 is not a public record pursuant to G.S. 132-1, is not subject to subpoena or discovery or any  
19 other use in civil proceedings, and except as otherwise provided below may only be used (i) for  
20 investigative or evidentiary purposes related to violations of State or federal ~~law and law~~, (ii)  
21 for regulatory activities, activities, or (iii) to inform medical records and clinical care. Except as  
22 otherwise provided by this section, prescription information shall not be disclosed or  
23 disseminated to any person or entity by any person or entity authorized to review prescription  
24 information.

25 ...

26 (c) The Department shall release data in the controlled substances reporting system to  
27 the following persons only:

28 ...

- 29 (8) Any county medical examiner appointed by the Chief Medical Examiner  
30 pursuant to G.S. 130A-382 and the Chief Medical Examiner, for the purpose  
31 of investigating the death of an individual.
- 32 (9) The federal Drug Enforcement Administration's Office of Diversion Control.
- 33 (10) The North Carolina Health Information Exchange (NC HIE), established  
34 under Article 29A of this Chapter, through Web-service calls.

35 ...."

36 (b) The Department of Health and Human Services shall adopt appropriate policies and  
37 procedures documenting and supporting the additional functionality and expanded access added  
38 by subsection (a) of this section for the Controlled Substances Reporting System (CSRS) for  
39 the entities added to G.S. 90-113.74(c) by subsection (a) of this section and shall amend its  
40 contract with the vendor that operates the CSRS to support the additional functionality and  
41 expanded access to the CSRS.

42 **SECTION 4.** Improve Controlled Substances Reporting System Contract.

43 (a) The Department of Health and Human Services (DHHS) shall modify the contract  
44 for the Controlled Substances Reporting System (CSRS) to improve performance, establish  
45 user access controls, establish data security protocols, and ensure availability of data for  
46 advanced analytics. Specifically, the contract shall be modified to include the following:

- 47 (1) A connection to the North Carolina Health Information Exchange (NC HIE).
- 48 (2) The establishment of interstate connectivity. DHHS shall execute a  
49 memorandum of understanding with the National Association of Boards of  
50 Pharmacy to participate in PMP InterConnect.
- 51 (3) A system feature requiring users to update account information annually.

- 1 (4) Confirmation of prescriber number validity by cross-referencing CSRS users  
2 with DEA numbers to ensure access is limited to users with valid, up-to-date  
3 information.  
4 (5) Data security protocols that meet or exceed the Federal Information  
5 Processing Standards (FIPS) established by the National Institute of  
6 Standards and Technology (NIST).  
7 (6) The quarterly transfer of a copy of the complete CSRS database to DHHS.  
8 Transferred data must be encrypted, include identified and deidentified  
9 cases, and be conducted through standard file transfer protocol.  
10 (7) Up to five ad hoc reports per month from the contractor that DHHS staff  
11 cannot produce through the online system.

12 (b) DHHS shall complete the contract modifications required by subsection (a) of this  
13 section by December 31, 2014. DHHS shall report by November 15, 2014, to the Joint  
14 Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight  
15 Committee on Health and Human Services regarding the progress to modify the contract.

16 (c) DHHS shall apply for grant funding from the National Association of Boards of  
17 Pharmacy to establish the connection to PMP InterConnect. The Department shall request  
18 forty-thousand thirty-five dollars (\$40,035) to establish the initial interface for PMP  
19 InterConnect and thirty thousand dollars (\$30,000) for two years of ongoing service,  
20 maintenance and support for PMP InterConnect in order to create interstate connectivity for the  
21 drug monitoring program as required by subdivision (2) of subsection (a) of this section.

22 (d) In order to support certain requirements of subsection (a) of this section, the  
23 following appropriations are made from the General Fund to DHHS:

- 24 (1) Five thousand one hundred dollars (\$5,100) for fiscal year 2014-2015 for the  
25 purpose of connecting the CSRS and the NC HIE, as required by subdivision  
26 (1) of subsection (a) of this section.  
27 (2) The sum of fifteen thousand dollars (\$15,000) for fiscal year 2014-2015,  
28 recurring, for the cost of maintaining a connection between the CSRS and  
29 the NC HIE, as required by subdivision (1) of subsection (a) of this section.  
30 (3) The sum of forty thousand thirty five dollars (\$40,035) for fiscal year  
31 2014-2015 to establish the initial interface for PMP InterConnect as required  
32 by subdivision (2) of subsection (a) of this section. This amount shall be  
33 adjusted or eliminated if DHHS is successful in obtaining grant awards or  
34 identifying other allowable receipts for this purpose. If receipts are used for  
35 this purpose, this nonrecurring appropriation shall revert to the General  
36 Fund.  
37 (4) The sum of fifteen thousand dollars (\$15,000) for fiscal year 2014-2015,  
38 nonrecurring, for the cost of annual service fees for the interstate connection  
39 for the drug monitoring program, as required by subdivision (2) of  
40 subsection (a) of this section. This amount shall be adjusted or eliminated if  
41 DHHS is successful in obtaining grant awards or identifying other allowable  
42 receipts for this purpose. If receipts are used for this purpose, this  
43 nonrecurring appropriation shall revert to the General Fund.

44 **SECTION 5. Expand Monitoring Capacity.**

45 (a) The North Carolina Controlled Substances Reporting System shall expand its  
46 monitoring capacity by establishing data use agreements with the Prescription Behavior  
47 Surveillance System. In order to participate, the CSRS shall establish a data use agreement with  
48 the Center of Excellence at Brandeis University no later than January 1, 2015.

49 (b) Beginning September 1, 2015, and every two years thereafter, the Division of  
50 Mental Health, Developmental Disabilities, and Substance Abuse Services of the Department  
51 of Health and Human Services shall report on its participation with the Prescription Behavior

1 Surveillance System to the Joint Legislative Oversight Committee on Health and Human  
2 Services and the Joint Legislative Oversight Committee on Justice and Public Safety.

3 **SECTION 6. Medicaid Lock-In Program.**

4 The Division of Medical Assistance of the Department of Health and Human Services  
5 (DMA) shall take the following steps to improve the effectiveness and efficiency of the  
6 Medicaid lock-in program:

- 7 (1) Establish written procedures for the operation of the lock-in program,  
8 including specifying the responsibilities of DMA and the program  
9 contractor.
- 10 (2) Establish procedures for the sharing of bulk data with the Controlled  
11 Substances Regulatory Branch.
- 12 (3) In consultation with the Physicians Advisory Group, extend lock-in duration  
13 to two years and revise program eligibility criteria to align the program with  
14 the statewide strategic goals for preventing prescription drug abuse. DMA  
15 shall report an estimate of the cost-savings from the revisions to the  
16 eligibility criteria to the Joint Legislative Program Evaluation Oversight  
17 Committee and the Joint Legislative Oversight Committee on Health and  
18 Human Services within one year of the lock-in program again becoming  
19 operational.
- 20 (4) Develop a Web site and communication materials to inform lock-in  
21 enrollees, prescribers, pharmacists, and emergency room health care  
22 providers about the program.
- 23 (5) Increase program capacity to ensure that all individuals who meet program  
24 criteria are locked in.
- 25 (6) Conduct an audit of the lock-in program within six months of the lock-in  
26 program again becoming operational in order to evaluate the effectiveness of  
27 program restrictions in preventing overutilization of controlled substances,  
28 identify any program vulnerabilities, and address whether there is evidence  
29 of any fraud or abuse within the program.

30 DMA shall report to the Joint Legislative Program Evaluation Oversight Committee by  
31 September 30, 2014, on its progress towards implementing all items included in this section.

32 **SECTION 7. Statewide Strategic Plan.**

33 (a) There is hereby created the Prescription Drug Abuse Advisory Committee, to be  
34 housed in and staffed by the Department of Health and Human Services (DHHS). The  
35 Committee shall develop and, through its members, implement a statewide strategic plan to  
36 combat the problem of prescription drug abuse. The Committee shall include representatives  
37 from the following, as well as any other persons designated by the Secretary of Health and  
38 Human Services:

- 39 (1) The Division of Medical Assistance, DHHS.
- 40 (2) The Division of Mental Health, Developmental Disabilities, and Substance  
41 Abuse Services, DHHS.
- 42 (3) The Division of Public Health, DHHS.
- 43 (4) The Office of Rural Health and Community Care, DHHS.
- 44 (5) The State Bureau of Investigation.
- 45 (6) The Attorney General's Office.
- 46 (7) The following health care regulatory boards with oversight of prescribers  
47 and dispensers of prescription drugs:
  - 48 a. North Carolina Board of Dental Examiners.
  - 49 b. North Carolina Board of Nursing.
  - 50 c. North Carolina Board of Podiatry Examiners.
  - 51 d. North Carolina Medical Board.

1 e. North Carolina Board of Pharmacy.

2 (8) The UNC Injury Prevention Research Center.

3 (9) The substance abuse treatment community.

4 (10) Community Care of North Carolina's (CCNC's) Project Lazarus.

5 (11) Governor's Institute on Substance Abuse, Inc.

6 (12) The Department of Insurance's drug take-back program.

7 After developing the strategic plan, the Committee shall be the State's steering committee to  
8 monitor achievement of strategic objectives and receive regular reports on progress made  
9 toward reducing prescription drug abuse in North Carolina.

10 (b) In developing the statewide strategic plan to combat the problem of prescription  
11 drug abuse, the Prescription Drug Abuse Advisory Committee shall, at a minimum, complete  
12 the following steps:

13 (1) Identify a mission and vision for North Carolina's system to reduce and  
14 prevent prescription drug abuse.

15 (2) Scan the internal and external environment for the system's strengths,  
16 weaknesses, opportunities, and challenges (a SWOC analysis).

17 (3) Compare threats and opportunities to the system's ability to meet challenges  
18 and seize opportunities (a GAP analysis).

19 (4) Identify strategic issues based on SWOC and GAP analyses.

20 (5) Formulate strategies and resources for addressing these issues.

21 (c) The strategic plan for reducing prescription drug abuse shall include three to five  
22 strategic goals that are outcome-oriented and measureable. Each goal must be connected with  
23 objectives supported by the following four mechanisms of the system:

24 (1) Oversight and regulation of prescribers and dispensers by state health care  
25 regulatory boards.

26 (2) Operation of the Controlled Substances Reporting System.

27 (3) Operation of the Medicaid lock-in program to review behavior of patients  
28 with high use of prescribed controlled substances.

29 (4) Enforcement of state laws for the misuse and diversion of controlled  
30 substances.

31 (5) Any other appropriate mechanism identified by the Committee.

32 (d) DHHS, in consultation with the Prescription Drug Abuse Advisory Committee, shall  
33 develop and implement a formalized performance management system that connects the goals  
34 and objectives identified in the statewide strategic plan to operations of the Controlled  
35 Substances Reporting System and Medicaid lock-in program, law enforcement activities, and  
36 oversight of prescribers and dispensers. The performance management system must be  
37 designed to monitor progress toward achieving goals and objectives and must recommend  
38 actions to be taken when performance falls short.

39 (e) Beginning on December 1, 2015, and annually thereafter, DHHS shall submit an  
40 annual report on the performance of North Carolina's system for monitoring prescription drug  
41 abuse to the Joint Legislative Oversight Committee on Health and Human Services and the  
42 Joint Legislative Oversight Committee on Justice and Public Safety.

43 **SECTION 8.** This act is effective when it becomes law.